(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 March 2004 (11.03.2004)

PCT

(10) International Publication Number
WO 2004/019820 A1

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number: PCT/US2003/022979

(22) International Filing Date: 24 July 2003 (24.07.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/231,598 30 August 2002 (30.08.2002) US

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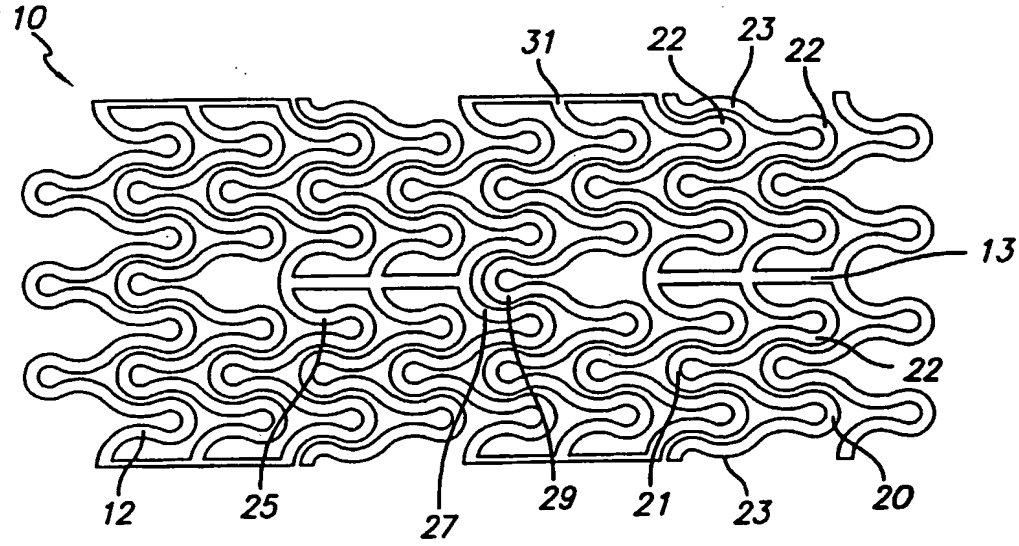
(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STENT WITH NESTED RINGS



(57) Abstract: An expandable stent for implantation in a body lumen, such as an artery, consisting of radially expandable cylindrical rings (12) nested within each other and generally aligned on a common longitudinal stmt axis. The rings are interconnected by one or more interconnecting links placed so that the stmt is flexible in the longitudinal direction while providing high degrees of radial strength and vessel scaffolding.

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STENT WITH NESTED RINGS

BACKGROUND OF THE INVENTION

This invention relates to expandable endoprosthesis devices, generally known as stents, which are designed for implantation in a patient's body lumen, such as blood vessels to maintain the patency thereof. These devices are particularly useful in the treatment and repair of blood vessels after a stenosis has been compressed by percutaneous transluminal coronary angioplasty (PTCA), or percutaneous transluminal angioplasty (PTA), or removed by atherectomy or other means.

Stents are generally cylindrically-shaped devices which function to hold open and sometimes expand a segment of a blood vessel or other lumen such as a coronary artery. They are particularly suitable for use to support the lumen or hold back a dissected arterial lining which can occlude the fluid passageway therethrough.

A variety of devices are known in the art for use as stents and have included coiled wires in a variety of patterns that are expanded after being placed intraluminally on a balloon catheter; helically wound coiled springs manufactured from an expandable heat sensitive metal; and self expanding stents inserted in a compressed state and shaped in a zigzag pattern. One of the difficulties encountered using prior stents involved maintaining the radial rigidity needed to hold open a body lumen while at the same time maintaining the longitudinal flexibility of the stent to facilitate its delivery and accommodate the often tortuous path of the body lumen.

Another problem area has been the limiting range of expandability. Certain prior art stents expand only to a limited degree due to the uneven stresses created upon the stents during radial expansion. This necessitates providing stents with a variety of diameters, thus increasing the cost of manufacture. Additionally, having a stent with a wider range of expandability allows the physician to redilate the stent if the original vessel size was miscalculated.

Another problem with the prior art stents has been contraction of the stent along its longitudinal axis upon radial expansion of the stent. This can cause placement problems within the artery during expansion.

Another problem has been inadequate vessel wall coverage. This can lead to portions of the stented area of the vessel to develop restenosis within the stent.

Various means have been described to deliver and implant stents. One method frequently described for delivering a stent to a desired intraluminal location includes mounting the expandable stent on an expandable member, such as a balloon, provided on the distal end of an intravascular catheter, advancing the catheter to the desired location within the patient's body lumen, inflating the balloon on the catheter to expand the stent into a permanent expanded condition and then deflating the balloon and removing the catheter.

What has been needed is a stent which has an enhanced degree of flexibility so that it can be readily advanced through tortuous passageways and radially expanded over a wider range of diameters. The expanded stent must have adequate structural strength (hoop strength) to hold open the body lumen in which it is expanded and a high degree of vessel wall coverage. The present invention satisfies this need.

SUMMARY OF THE INVENTION

The present invention is directed to stents having a high degree of flexibility along their longitudinal axis to facilitate delivery through tortuous body lumens, but which remain highly stable when expanded radially, to maintain the patency of a body lumen such as an artery or other vessel when implanted therein. The unique nested configuration of the stents of the instant invention permits a higher degree of vessel wall coverage, lower crimped profile, and optimum flexibility as compared to prior art stents with equivalent length and size dimensions.

Each of the different embodiments of the stent of the present invention includes adjacent cylindrical rings which are generally expandable in the radial direction and arranged in alignment along a longitudinal stent axis. The cylindrical

rings are formed with a variety of undulations transverse to the longitudinal axis and containing alternating peaks and valleys. The undulations contain varying degrees of curvature in regions of the peaks and valleys and are adapted so that the radial expansion of the cylindrical rings are generally uniform around their circumferences during expansion of the stents from their contracted conditions to their expanded conditions. In all embodiments, the undulations within the rings generally have an upper and lower section for each peak and valley. The lower female section of one ring is configured to accept the upper male section of an adjacent ring positioned below. Similarly, the upper male section of one ring is configured to nest within the lower female section of an adjacent ring positioned above. This relationship between undulations nests adjacent rings together and provides a high degree of scaffolding without decreasing either longitudinal flexibility or radial strength as mentioned above.

At least one link extends between adjacent cylindrical rings and connects them to one another. The interconnecting links insure minimal longitudinal contraction during radial expansion in the body vessel along with providing structural support to the stent. The links are configured to minimize the potentially limiting effects that conventional links have on conventional stents with respect to longitudinal flexibility. To counter the need for a vast number of links to align and support adjacent rings, the stent of the present invention incorporates nested rings as detailed above. The additional vessel surface area covered by the nested rings lessons the link's requirement to act as a structural member. Accordingly, fewer links or smaller links can be used in the present invention without sacrificing radial strength and longitudinal flexibility when compared to conventional, unnested-ring stents. The smaller portion of the stent including the links enables the stent to cover more vessel surface area with the large cross-sections of the undulations in the nested rings.

The resulting stent structures are a series of radially expandable cylindrical rings which are nested together so that small dissections in the wall of a body lumen may be pressed back into position against the luminal wall, while maintaining the

longitudinal flexibility of the stent both when being negotiated through the body lumens in their unexpanded state and when expanded into position. The undulations of the cylindrical rings allow for an even expansion around the circumference by accounting for the relative differences in stress created by the radial expansion of the cylindrical rings. Each of the individual cylindrical rings may rotate slightly relative to their adjacent cylindrical elements without significant deformation, cumulatively providing stents which are flexible along their length and about their longitudinal axis, but which are still very stable in the radial direction in order to resist collapse after expansion.

The cylindrical rings are nested in a pattern that provides a greater surface area than non-nested stents and as a result, the nested ring stent of the present invention is ideal for use as a drug delivery stent. Any number of therapeutic drugs can be loaded onto the nested ring stent to provide treatment to a vessel, such as a coronary artery. The present invention drug delivery stent is particularly useful in reducing the likelihood of the development of restenosis.

Each of the embodiments of the invention can be readily delivered to the desired luminal location by mounting them on an expandable member of a delivery catheter, for example a balloon, and passing the catheter-stent assembly through the body lumen to the implantation site. A variety of means for securing the stents to the expandable member on the catheter for delivery to the desired location is available. It is presently preferred to compress or crimp the stent onto the unexpanded balloon. Other means to secure the stent to the balloon include providing ridges or collars on the inflatable member to restrain lateral movement, using bioabsorbable temporary adhesives, or a retractable sheath to cover the stent during delivery through a body lumen.

The presently preferred structures for the expandable cylindrical rings which form the stents of the present invention generally have a plurality of circumferential undulations containing a plurality of alternating peaks and valleys and bar arms. The peaks and valleys are formed in generally U-, V-, and W-shaped patterns and aligned along the longitudinal axis. The longitudinally arranged components of the

rings are referred to as bar arms. The length of the bar arms can be varied between different embodiments. The bar arms typically have a straight portion that is generally aligned with the longitudinal axis and one or more curved portions. The curved portions of the bar arms are positioned to correspond with an adjacent ring portion or undulation. In other words, to facilitate a lower crimped profile for the stent, the bar arms have curved portions that are circumferentially adjacent the undulations of an adjacent, nested ring.

While the cylindrical rings and links generally are not separate structures, they have been conveniently referred to as rings and links for ease of identification. Further, the cylindrical rings can be thought of as comprising a series of U-, V-, or W-shaped structures in a repeating pattern. While the cylindrical rings are not divided up or segmented into U's, V's, and W's, the pattern of cylindrical rings resemble such configuration. The U's, V's, and W's promote flexibility in the stent primarily by flexing and may tip radially outwardly as the stent is delivered through a tortuous vessel.

The undulations of the cylindrical rings can have different degrees of curvature and angles of adjacent peaks and valleys to compensate for the expansive properties of the peaks and valleys. The cylindrical rings of the stents are plastically deformed when expanded (except with NiTi alloys) so that the stents will remain in the expanded condition and therefore they must be sufficiently rigid when expanded to prevent the collapse thereof in use.

With stents formed from super-elastic nickel-titanium (NiTi) alloys, the expansion occurs when the stress of compression is removed. This allows the phase transformation from martensite back to austenite to occur, and as a result the stent expands.

After the stents are expanded some of the peaks and/or valleys may, but not necessarily, tip outwardly and embed in the vessel wall. Thus, after expansion, the stents may not have a smooth outer wall surface, rather they have small projections which embed in the vessel wall and aid in retaining the stents in place in the vessel.

The links interconnecting adjacent cylindrical rings may have cross-sections similar to the cross-sections of the undulations within the rings. The links may also be formed in a unitary structure with the expandable cylindrical rings formed from the same intermediate product, such as a tubular element, or they may be formed independently and mechanically secured between the expandable cylindrical rings.

Preferably, the number, shape and location of the links and bar arms can be varied in order to develop the desired longitudinal flexibility in the stent structure both in the unexpanded as well as the expanded condition. These properties are important to minimize alteration of the natural physiology of the body lumen into which the stent is implanted and to maintain the compliance of the body lumen which is internally supported by the stent. Generally, the greater the longitudinal flexibility of the stents, the easier and the more safely they can be delivered to the implantation site, especially where the implantation site is on a curved section of a body lumen, such as a coronary artery or a peripheral blood vessel, and especially saphenous veins and larger vessels.

The stent may be formed from a tube by laser cutting the pattern of cylindrical rings and undulating links in the tube, by individually forming wire rings and laser welding them together, and by laser cutting a flat metal sheet in the pattern of the cylindrical rings and links, and then rolling the pattern into the shape of the tubular stent and providing a longitudinal weld to form the stent.

Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view, partially in section, depicting the stent embodying features of the invention mounted on a delivery catheter and disposed within a vessel.

FIG. 2 is an elevational view, partially in section, similar to that shown in FIG. 1, wherein the stent is expanded within a vessel, pressing the lining against the vessel wall.

FIG. 3 is an elevational view, partially in section, showing the expanded stent within the vessel after withdrawal of the delivery catheter.

FIG. 4 is a plan view of a flattened section of one embodiment of a stent of the invention which illustrates the undulating pattern and the varying number of interconnecting links of the stent.

FIG. 5 is a perspective view of the stent of FIG. 4 in its expanded state depicting the serpentine pattern along the peaks and valleys that form the cylindrical rings of the stent.

FIG. 6 is a plan view of a flattened section of one embodiment of a stent of the invention including generally U-shaped ring undulations.

FIG. 7 is a plan view of a flattened section of one embodiment of a stent of the invention.

FIG. 8 is a plan view of a flattened section of one embodiment of a stent of the invention including two different link configurations.

FIG. 9 is a plan view of a flattened section of one embodiment of a stent of the invention also including two different link configurations.

FIG. 10 is a plan view of a flattened section of one embodiment of a stent of the invention including a W-link configuration.

FIG. 10A is an enlarged partial section of a bar arm taken from FIG. 10.

FIG. 11 is a plan view of a flattened section of one embodiment of a stent of the invention including a highly nested configuration.

FIG. 12 is a plan view of a flattened section of one embodiment of a stent of the invention also including a highly nested configuration.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention stent improves on existing stents by providing a longitudinally flexible stent having a nested ring pattern and interconnecting links.

In addition to providing longitudinal flexibility, the stent of the present invention also provides radial rigidity and a high degree of scaffolding of a vessel wall, such as a coronary artery. The design of the nested rings, links, and their placement within the stent provides for uniform scaffolding and a high degree of vessel wall coverage. The nested ring pattern also is ideal for use as a drug delivery stent.

Before describing in detail an exemplary embodiment of a nested stent in accordance with the present invention, it is instructive to briefly describe a typical stent implantation procedure and the vascular conditions which are typically treated with stents.

FIG. 1 illustrates a first embodiment of a stent 10 incorporating features of the invention which is mounted onto a delivery catheter 11. The stent generally comprises a plurality of radially expandable cylindrical rings 12 nested within each other and disposed generally coaxially and interconnected by links 13 disposed between adjacent cylindrical rings. The delivery catheter has an expandable portion or balloon 14 for expanding stent within an artery 15 or other vessel. The artery, as shown in FIG. 1, has a dissected lining 16 which occludes a portion of the arterial passageway.

The delivery catheter 11 onto which the stent 10 is mounted, is essentially the same as a conventional balloon dilatation catheter for angioplasty procedures. The balloon 14 may be formed of suitable materials such as polyethylene, polyethylene terephthalate, polyvinyl chloride, nylon and inomers such as Surlyn® manufactured by the Polymer Products Division of the Du Pont Company. Other polymers may also be used. In order for the stent to remain in place on the balloon during delivery to the site of the damage within the artery 15, the stent is compressed onto the balloon. A retractable protective delivery sleeve 17 may be provided to further ensure that the stent stays in place on the expandable portion of the delivery catheter 11 and prevents abrasion of the body lumen by the open surface of the stent during delivery to the desired arterial location. Other means for securing the stent onto the balloon also may be used, such as providing collars or ridges on the ends of the working portion, i.e., the cylindrical portion, of the

balloon. Each radially expandable cylindrical ring 12 of the stent may be independently expanded, therefore the stent and the balloon may be provided with an inflated shape other than cylindrical, e.g., tapered, to facilitate implantation of the stent in a variety of body lumen shapes.

In a preferred embodiment, the delivery of the stent 10 is accomplished in the following manner. The stent is first mounted onto an inflatable balloon 14 on the distal extremity of the delivery catheter 11 and is "crimped" down onto the balloon to ensure a low profile. The catheter-stent assembly can be introduced within the patient's vasculature in a conventional Seldinger technique through a guiding catheter (not shown). A guide wire 18 is advanced through the damaged arterial section and then the catheter-stent assembly is advanced over the guide wire within the artery 15. The balloon is expanded, expanding the stent against the inside of the artery, which is illustrated in FIG. 2. While not shown in the drawing, the artery is preferably expanded slightly by the expansion of the stent to seat or otherwise fix the stent to prevent movement. In some circumstances during the treatment of stenosis portions of an artery, the artery may have to be expanded considerably in order to facilitate passage of blood or other fluid there through. The stent can be used for many purposes, such as supporting the vessel, reducing the likelihood of restenosis, or to assist in attaching a vascular graft (not shown) when repairing an aortic abdominal aneurysm.

The stent 10 serves to hold open the artery 15 after the catheter 11 is withdrawn, as illustrated in FIG. 3. Due to the formation of the stent from an elongated tubular member, the undulating component of the cylindrical rings 12 of the stent is relatively flat in transverse cross-section, so that when the stent is expanded, the cylindrical rings are pressed into the wall of the artery and as a result do not interfere with the blood flow through the artery. The cylindrical rings of the stent which are pressed into the wall of the artery will eventually be covered with endothelial cell growth which further minimizes blood flow turbulence. The undulating pattern and nested configuration of the cylindrical rings provide good tacking characteristics to prevent stent movement within the artery. Furthermore,

the nested cylindrical rings at regular intervals provide uniform support for the wall of the artery, and consequently are well adapted to tack up and hold in place small flaps or dissections 16 in the wall of the artery as illustrated in FIGS. 2 and 3.

For the purposes of this description, it is beneficial to refer to this exemplary embodiment of the stent as being composed of metallic cylindrical rings 12 and metallic links 13. The rings have a first, crimped delivery diameter and a second, larger implanted diameter. They are each expandable in the radial direction and aligned together along the longitudinal axis of the stent. The links 13 interconnect adjacent rings longitudinally.

The properties of the stent 10 may vary by alteration of the cylindrical rings 12 or links 13. FIG. 4 illustrates a plan view of a flattened section of the stent in its crimped state. The cylindrical rings have an undulating shape similar to an hourglass and include peaks 20 and valleys 21. The longitudinal components of the undulations are comprised of bar arms 19 in FIG. 4. The particular pattern and how many undulations, or the amplitude of the undulations, are chosen to fill particular mechanical requirements for the stent, such as radial stiffness, longitudinal flexibility and vessel wall coverage. In this embodiment, all of the peaks and all of the valleys are respectively aligned longitudinally. The number of cylindrical rings incorporated into the stent can also be varied according to design requirements similar to those mentioned above. The links are substantially linear shaped, although they can be varied for design requirements. As with the rings, undulations and varying amplitudes of undulations in the links may be chosen to fill mechanical requirements of the stent.

The stent 10 also incorporates horseshoe-shaped undulations 25 that connect links 13 between adjacent rings 12. The uppermost undulation accepts the valley 29 of the adjacent ring 31. A pattern which does not incorporate these horseshoe-shaped components is also contemplated. In order for this configuration to work effectively, the width of either the undulations within the rings or the links will be decreased to ensure proper fitment.

In this embodiment, both the peaks 20 and the valleys 21 are aligned respectively along the stent's longitudinal axis. Each peak 20 has an uppermost 22 and lowermost 23 component. In order for adjacent rings to nest within each other, the uppermost component fits within the lowermost part of an adjacent ring. The compact arrangement of the rings 12 and links 13 enables the stent 10 to provide better vessel wall coverage than a similarly sized stent with similarly shaped members, which are not nested. The minimal amount and unique arrangement of the links is beneficial when delivering and implementing the stent in tortuous vessels due to the flexibility with which the minimum number of links provide the stent.

In all embodiments, the undulations within the rings generally have an upper and lower section for each peak and valley. The lower female section of one ring is configured to accept the upper male section of an adjacent ring positioned below. Similarly, the upper male section of one ring is configured to nest within the lower female section of an adjacent ring positioned above. This relationship between undulations nests adjacent rings together and provides a high degree of scaffolding without decreasing either longitudinal flexibility or radial strength as mentioned above.

With reference to FIG. 5 which shows the stent 10 in its expanded form, the cylindrical rings 12 are in the form of undulating portions. The undulating portion is made up of a plurality of hourglass-shaped members including peaks 20 and valleys 21 having radii that more evenly distribute expansion forces over the various members. After the cylindrical rings have been radially expanded, outwardly projecting edges 24,26 may be formed. That is, during radial expansion some of the peaks and valleys may tip radially outwardly thereby each forming outwardly projecting edges, respectively. These outwardly projecting edges can provide for a roughened outer wall surface of the stent and assist in implanting the stent in the vascular wall by embedding into the vascular wall. Depending upon the dimensions of stent and the thickness of the various members making up the

serpentine pattern, any of the peaks and valleys can tip radially outwardly to form the projecting edges.

The links are configured to minimize the potentially limiting effects that conventional links have on conventional stents with respect to longitudinal flexibility. To counter the need for a vast number of links to align and support adjacent rings, the stent of the present invention incorporates nested rings as detailed above. The additional vessel surface area covered by the nested rings lessons the requirement of the links to act as structural members. Accordingly, fewer links or smaller links can be used in the present invention without sacrificing radial strength and longitudinal flexibility when compared to conventional, unnested ring stents. The smaller portion of the stent including the links enables the stent to cover more vessel surface area with the large cross-sections of the undulations in the nested rings.

Cylindrical rings 12 can be nested such that adjacent rings slightly overlap in the longitudinal direction so that one or more rings are slightly to completely nested within adjacent rings and so on. The degree of nesting can be dictated by the pattern of undulations, the length of each cylindrical ring, the number of undulations in the rings, the thickness of the rings, and the radius of curvature, all in conjunction with the crimped or delivery diameter of the stent. If the rings are substantially nested one within the other, it may be difficult to crimp the stent to an appropriate delivery diameter without overlapping. It is also contemplated that the rings may be slightly to completely nested even after the stent is expanded, which enhances vessel wall coverage. In some circumstances, it may not be desirable to heavily nest each ring within another, which is also contemplated by the invention.

The stent patterns shown in FIGS. 1-5 are for illustration purposes only and can vary in shape and size to accommodate different vessels or body lumens. Thus, the rings and links can have any structural shapes and are not limited to the aforedescribed undulating rings with hourglass-shaped members with peaks 20 and valleys 21 and linear links 13. For example, a variety of configurations incorporating generally S-, Y-, W-, and Z-shaped rings and links along with sine

waves, loops, and sharp angles can be utilized according to design requirements. The cylindrical rings and links can also be formed with shape memory alloys, and radiopacitly enhanced.

The multitude of stent embodiments illustrated in FIGS. 6 through 14 are similar to the above embodiment illustrated in FIGS. 1-5 in that each embodiment has essentially a plurality of interconnected rings, the rings being nested to a degree within each other.

With reference to FIG. 6, the stent 40 comprises a series of cylindrical rings 36 incorporating bar arms 34 similar to the rings 12 shown in FIGS. 1-5. Here, the rings have undulations with a greater degree of angulation. Rather than resembling an hourglass, like the undulations of the rings 12 of FIGS. 1-5, the undulations of the rings illustrated in FIG. 6 are V-shaped 31. The undulations include peaks 30, valleys 32, and uppermost 38 and lowermost 39 components. The peaks are configured to nest with the lower portion of an undulation of an adjacent ring.

The links 33 of the stent shown in FIG. 6 are short in comparison to the links 13 shown in FIGS. 1-5. This unique link configuration permits a different and possibly more flexible assembly of undulations in each ring 36. As illustrated in FIG. 6, the series of rings are attached together with the short links such that some undulations within each ring have shallower valleys 35 to accept the valleys 32 of an adjacent ring. Additionally, the shallow valley 35 is formed slightly differently with a substantially W-shaped structure 37. In order to maximize longitudinal flexibility, there is only one link connecting adjacently situated rings.

Referring now to FIG. 7, the stent 50 incorporates rings 46 including short bar arms 45, the rings connected adjacently with a combination of short links 43. The short bar arms help to decrease the amount of protrusion of the undulations when the stent is bent. Similar to the stent shown in FIG. 6, the undulations within the rings are angulated and consist of peaks 41, valleys 42, and lowermost portions 44 and uppermost portions 49. The peaks nest within the lower portions of adjacent rings and provide the stent with a high degree of vessel wall coverage. Similar to the stent 40 shown in FIG. 6, the stent 50 of the present embodiment incorporates

one shallow valley in each ring which is connected to the valley 42 of an adjacent ring through a short link. The shallow valley is also formed in a substantially W-shaped pattern 47 similar to the valley 35 shown in FIG. 6.

The stent 60 shown in FIG. 8 is similar to the stent 50 shown in FIG. 7 in that it incorporates rings 56 including short bar arms 58, the rings connected adjacently with a combination of short links 53 which are longitudinally aligned. In order to reduce potential shortening of the stent during expansion, there are one or more additional long links 59 when compared to the stent 50 shown in FIG. 7. The stent also incorporates a variety of different undulations. A first series of W-shaped undulations 55 are configured similarly to the W-shaped undulations 47 shown in FIG. 7 and like the undulations shown in FIG. 7, connect to the short links of the present embodiment. Unlike the undulations in FIG. 6, however, undulations 55 are arranged in two directions along the stent's longitudinal axis. A second plurality of smaller W-shaped undulations 57 connect the plurality of long links of the present embodiment. Experimentation shows that incorporating more links 56 into the existing embodiment significantly increases the crimped profile.

The stent 70 shown in FIG. 9 also incorporates a series of long links 63 and short bar arms 68. The links here differ from those in FIG. 8 because they are longer. The increase in link length may help overall stent flexibility. Similar to FIG. 8, the links are aligned along the stent's longitudinal axis. The stent also incorporates a variety of different undulations incorporated into the rings 66. A first series of W-shaped undulations 62 are connected to links 63 such that the link does not form part of the W-shape. A second series of W-shaped undulations 65 connects to the long links. A plurality of a third series of smaller W-shaped undulations 67 also connects to the long links. All types of aforementioned W-shaped undulations can be arranged in either similar or opposing directions along the stent longitudinal axis.

The stent 80 depicted in FIG. 10 incorporates a series of rings 71 and links 72 interconnecting adjacent rings and bar arms 73. Preferably, the bar arms are relatively short so that the length of each ring is short to maximize the number of

rings per given stent length. For example, a typical coronary artery stent length would be 15mm or 18 mm. Thus, in the FIG. 10 embodiment, twenty-three rings are depicted for an 18-mm-long stent. In this embodiment, the links are about one-half as long as the bar arms, and the links can be even less than half as long as the bar arms. Shorter rings enhance longitudinal flexibility of the stent. To further enhance longitudinal flexibility, the links 72 are approximately one-half as long as a ring, and may even be less than half as long as a ring. In order to reduce the crimped profile, the number of links in each ring is two in this embodiment, but may be more or less to suit a particular application. Further, the links in one ring point in different axial directions. For example, in this embodiment, the rings each include a first series of substantially W-shaped undulations 74 arranged in both directions along the stent's longitudinal axis whereby the links attach to connect adjacent rings. In other words, W-shaped undulations 74A point toward the stent distal end 75 and W-shaped undulations 74B point toward the stent proximal end 76. Similar to previous embodiments of the stent of the present invention, the links 72 are aligned along the stent longitudinal axis and alternate every other ring. The links are circumferentially offset within a ring, and are circumferentially offset from one ring to the next, which also enhances flexibility but does not sacrifice vessel wall coverage and hoop strength.

With continued reference to the stent 80 of FIG. 10, the undulations can be further described as having peaks 77 and valleys 78. The peaks are in phase and point in the same general direction toward the distal end 75, while the valleys are in phase and point generally toward the proximal end. The peaks and valleys have a generally U- or V-shaped portion 79 and will uniformly expand when the stent is expanded by balloon pressure. The stent also includes a Y-shaped portion 81 which has link 72 extending from the tip of an undulation to the base of a W-shaped undulation 74. The unique nested arrangement of the U-or V-shaped portions, Y-shaped portions, and W-shaped undulations provides for a highly flexible stent that provides a high amount of surface area for drug coating and a low crimped stent profile. The bar arms 73 typically have a straight portion 82 that is generally

aligned along the longitudinal axis and one or more curved portions 83. The curved portions of the bar arms are positioned to correspond with an adjacent ring portion or undulation, such as peaks 77 or valleys 78. In other words, to facilitate a lower crimped profile for the stent, the bar arms have curved portions that are circumferentially adjacent to the undulations of an adjacent, nested ring. As shown in FIG. 10, curved portions 83 are circumferentially adjacent to W-shaped undulations 74 of an adjacent ring.

In FIG. 10A, which is an enlarged portion of bar arm 73, it can be seen that section A is essentially a mirror image of section B. In each section, there is at least one straight portion 82 and one or more curved portions 83. The length of the straight portions can be adjusted to optimize stent expansion capabilities.

The stent 90 depicted in FIG. 11 is similar to the stent 10 shown in FIGS. 1-5 in terms of members 92 shaped similar to a longitudinal cross-sectional view of an hourglass. The links 94 are also similar, being formed in a substantially straight configuration. Differences include narrow undulations and a high degree of nesting as shown in FIG. 11. In this embodiment, adjacent rings 96,98 have narrow undulations completely nested within each other. This compact configuration provides excellent vessel wall coverage while maintaining flexibility through the use of only one link connecting adjacent rings.

The stent 100 shown in FIG. 12 also incorporates highly nested adjacent rings 102. Similar to other embodiments, the links 104 are also substantially straight. The nested portion of each ring incorporates a substantially circular member 106. In the portion of each ring which incorporates a link, the elongated circular member 108 is configured to accept the link.

The stents of the present invention can be made in many ways. However, the preferred method of making the stent is to cut a thin-walled tubular member, such as stainless steel tubing to remove portions of the tubing in the desired pattern for the stent, leaving relatively untouched the portions of the metallic tubing which are to form the stent. It is preferred to cut the tubing in the desired pattern by means of a machine-controlled laser, which is well known in the art.

The stent tubing may be made of suitable biocompatible material such as stainless steel, titanium, tungsten, tantalum, vanadium, cobalt chromium, gold, palladium, platinum, and iradium, super-elastic (nickel-titanium) NiTi alloys and even high strength thermoplastic polymers. The stent diameters are very small, so the tubing from which it is made must necessarily also have a small diameter. For PCTA applications, typically the stent has an outer diameter on the order of about 1.65 mm (0.065 inches) in the unexpanded condition, the same outer diameter of the hypotubing from which it is made, and can be expanded to an outer diameter of 5.08 mm (0.2 inches) or more. The wall thickness of the tubing is about 0.076 mm (0.003 inches). For stents implanted in other body lumens, such as PTA applications, the dimensions of the tubing are correspondingly larger. While it is preferred that the stents be made from laser cut tubing, those skilled in the art will realize that the stent can be laser cut from a flat sheet and then rolled up in a cylindrical configuration with the longitudinal edges welded to form a cylindrical member.

In the instance when the stents are made from plastic, the implanted stent may have to be heated within the arterial site where the stents are expanded to facilitate the expansion of the stent. Once expanded, it would then be cooled to retain its expanded state. The stent may be conveniently heated by heating the fluid within the balloon or the balloon itself directly by a known method.

The stents may also be made of materials such as super-elastic (sometimes called pseudo-elastic) nickel-titanium (NiTi) alloys. In this case the stent would be formed full size but deformed (e.g. compressed) to a smaller diameter onto the balloon of the delivery catheter to facilitate intraluminal delivery to a desired intraluminal site. The stress induced by the deformation transforms the stent from an austenite phase to a martensite phase, and upon release of the force when the stent reaches the desired intraluminal location, allows the stent to expand due to the transformation back to the more stable austenite phase. Further details of how NiTi super-elastic alloys operate can be found in U.S. Patent Nos. 4,665,906 (Jervis) and 5,067,957 (Jervis), incorporated herein by reference in their entirety.

The stent of the invention also can be coated with a drug or therapeutic agent. Further, it is well known that the stent (when made from a metal) may require a primer material coating such as a polymer to provide a substrate on which a drug or therapeutic agent is coated since some drugs and therapeutic agents do not readily adhere to a metallic surface. The drug or therapeutic agent can be combined with a coating or other medium used for controlled release rates of the drug or therapeutic agent. Examples of therapeutic agents or drugs that are suitable for use with the polymeric materials include sirolimus, everolimus, actinomycin D (ActD), taxol, paclitaxel, or derivatives and analogs thereof. Examples of agents include other antiproliferative substances as well as antineoplastic, antiinflammatory, antiplatelet, anticoagulant, antifibrin, antithrombin, antimitotic, antibiotic, and antioxidant substances. Examples of antineoplastics include taxol (paclitaxel and docetaxel). Further examples of therapeutic drugs or agents that can be combined with the polymeric materials include antiplatelets, anticoagulants, antifibrins, antithrombins, and antiproliferatives. Examples of antiplatelets, anticoagulants, antifibrins, and antithrombins include, but are not limited to, sodium heparin, low molecular weight heparin, hirudin, argatroban, forskolin, vapiprost, prostacyclin and prostacyclin analogs, dextran, D-phe-pro-arg-chloromethylketone (synthetic antithrombin), dipyridamole, glycoprotein IIb/IIIa platelet membrane receptor antagonist, recombinant hirudin, thrombin inhibitor (available from Biogen located in Cambridge, MA), and 7E-3B® (an antiplatelet drug from Centocor located in Malvern, PA). Examples of antimitotic agents include methotrexate, azathioprine, vincristine, vinblastine, fluorouracil, adriamycin, and mutamycin. Examples of cytostatic or antiproliferative agents include angiopeptin (a somatostatin analog from Ibsen located in the United Kingdom), angiotensin converting enzyme inhibitors such as Captopril® (available from Squibb located in New York, NY), Cilazapril® (available from Hoffman-LaRoche located in Basel, Switzerland), or Lisinopril® (available from Merck located in Whitehouse Station, NJ); calcium channel blockers (such as Nifedipine), colchicine, fibroblast growth factor (FGF) antagonists, fish oil (omega 3-fatty acid), histamine antagonists, Lovastatin® (an

inhibitor of HMG-CoA reductase, a cholesterol lowering drug from Merck), methotrexate, monoclonal antibodies (such as PDGF receptors), nitroprusside, phosphodiesterase inhibitors, prostaglandin inhibitor (available from GlaxoSmithKline located in United Kingdom), Seramin (a PDGF antagonist), serotonin blockers, steroids, thioprotease inhibitors, triazolopyrimidine (a PDGF antagonist), and nitric oxide. Other therapeutic drugs or agents which may be appropriate include alpha-interferon, genetically engineered epithelial cells, and dexamethasone.

While the foregoing therapeutic agents have been used to prevent or treat restenosis, they are provided by way of example and are not meant to be limiting, since other therapeutic drugs may be developed which are equally applicable for use with the present invention. The treatment of diseases using the above therapeutic agents are known in the art. Furthermore, the calculation of dosages, dosage rates and appropriate duration of treatment are previously known in the art.

While the invention has been illustrated and described herein in terms of its use as intravascular stents, it will be apparent to those skilled in the art that the stents can be used in other instances in all vessels in the body. Since the stents of the present invention have the novel feature of enhanced longitudinal flexibility due to their angulated undulations, they are particularly well suited for implantation in almost any vessel where such devices are used. This feature, coupled with limited longitudinal contraction of the stent when radially expanded, provides a highly desirable support member for all vessels in the body. Other modifications and improvements may be made without departing from the scope of the invention.

WHAT IS CLAIMED:

1. An intravascular stent, comprising:

a plurality of radially expandable, longitudinally aligned cylindrical rings with first delivery diameters and second implanted diameters;

a plurality of links interconnecting adjacent cylindrical rings;

wherein the cylindrical rings have undulations comprising peaks and valleys; and

wherein a plurality of the peaks of a first set of rings are longitudinally nested with a plurality of the valleys of a second set of adjacent rings.

2. The stent of claim 1, wherein at least some of the rings are connected with one link.

3. The stent of claim 1, wherein at least some of the rings are connected with two links.

4. The stent of claim 1, wherein at least some of the rings are connected with three links.

5. The stent of claim 1, wherein at least some of the undulations are generally hourglass-shaped.

6. The stent of claim 1, wherein more than one of the undulations are substantially circular.

7. The stent of claim 1, wherein a substantial portion of the adjacent rings are nested.

8. The stent of claim 1, wherein more than one of the undulations are generally horseshoe-shaped.

9. The stent of claim 1, wherein the links are longitudinally aligned successively among a set of three rings.

10. The stent of claim 1, wherein the undulations include U-shaped members.

11. The stent of claim 1, wherein the undulations include W-shaped members.

12. The stent of claim 1, wherein the undulations include V-shaped members.

13. The stent of claim 1, wherein the links comprise a first set of links and a second set of links.

14. The stent of claim 13, wherein the second set of links are longer than the first set of links.

15. The stent of claim 1, wherein the stent is self-expanding.

16. The stent of claim 15, wherein the material forming the cylindrical rings embodies shape memory material.

17. The stent of claim 16, wherein the shape memory material is a superelastic material.

18. The stent of claim 17, wherein the superelastic material is nickel-titanium.

19. The stent of claim 1, wherein the stent is biocompatible.

20. The stent of claim 1, wherein the stent is non-biodegradable.

21. The stent of claim 1, wherein the stent includes a material therein to enhance the radiopacity of the stent.

22. The stent of claim 1, wherein the stent is formed with substantially translucent members.

23. The stent of claim 1, wherein the stent may be expanded by force.

24. The stent of claim 1, wherein the metallic material forming the cylindrical rings and links is taken from the group of metals consisting of stainless steel, titanium, tantalum, nickel titanium, cobalt-chromium, gold, palladium, platinum and iradium.

25. The stent of claim 1, wherein at least a portion of the stent is coated with a drug.

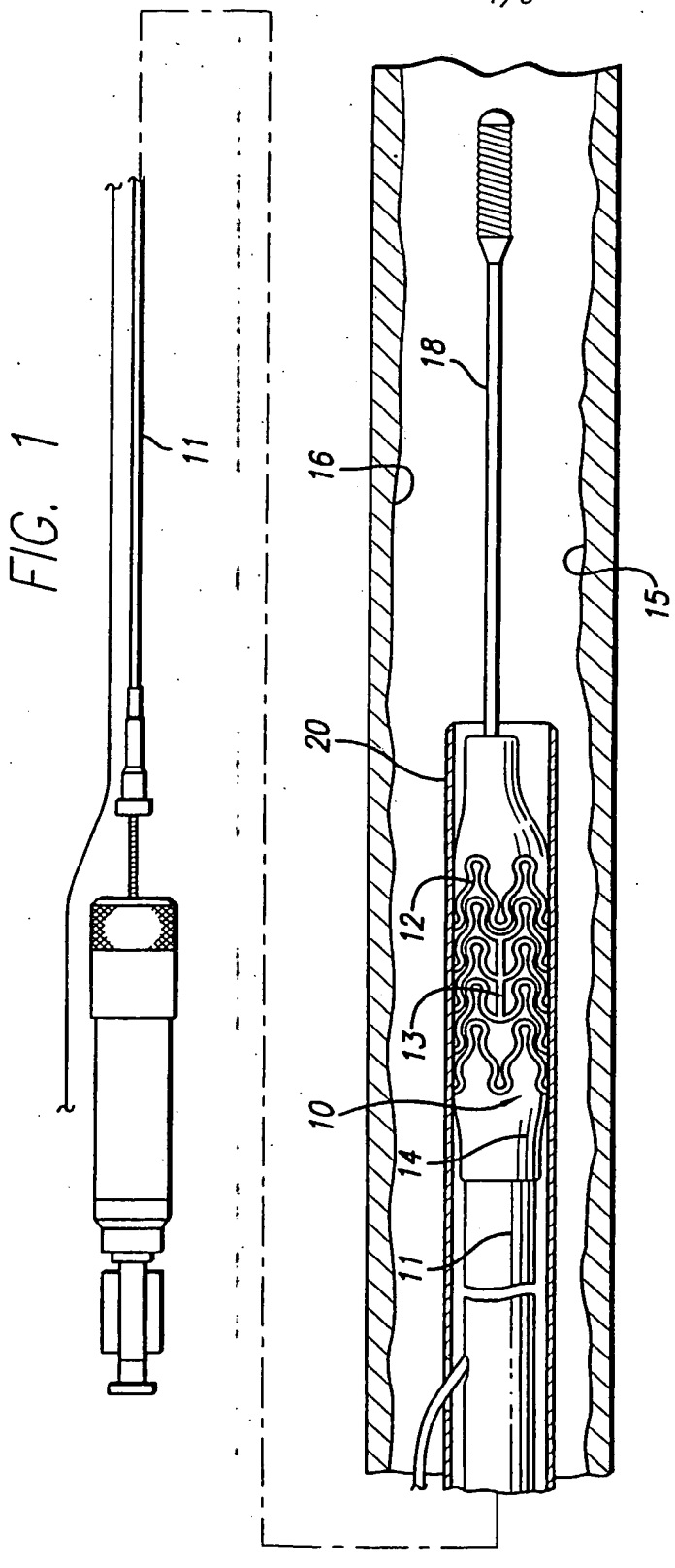


FIG. 1

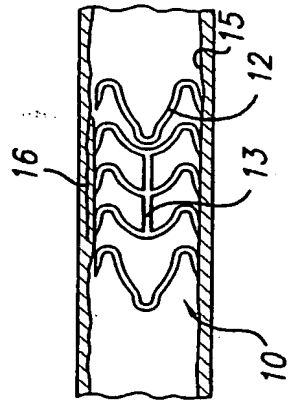


FIG. 3

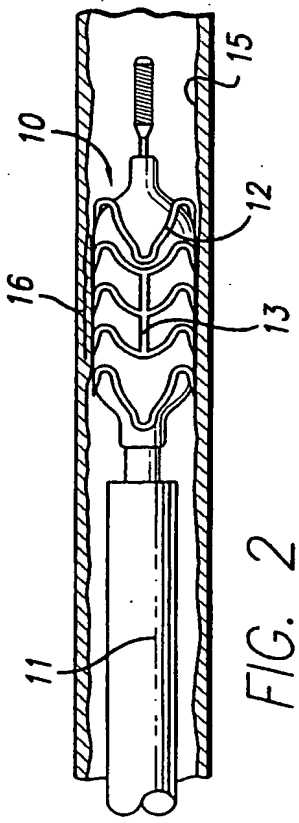
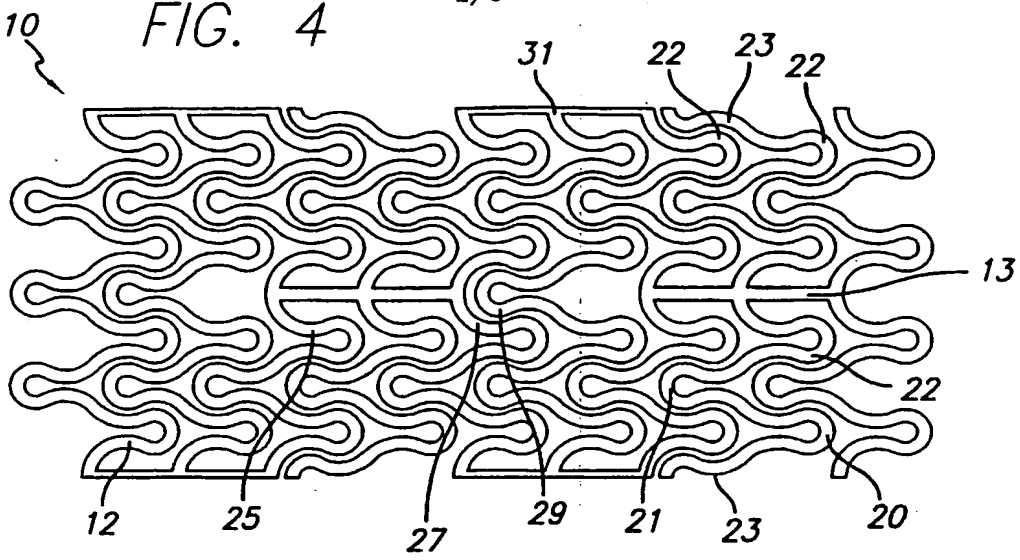


FIG. 2

FIG. 4



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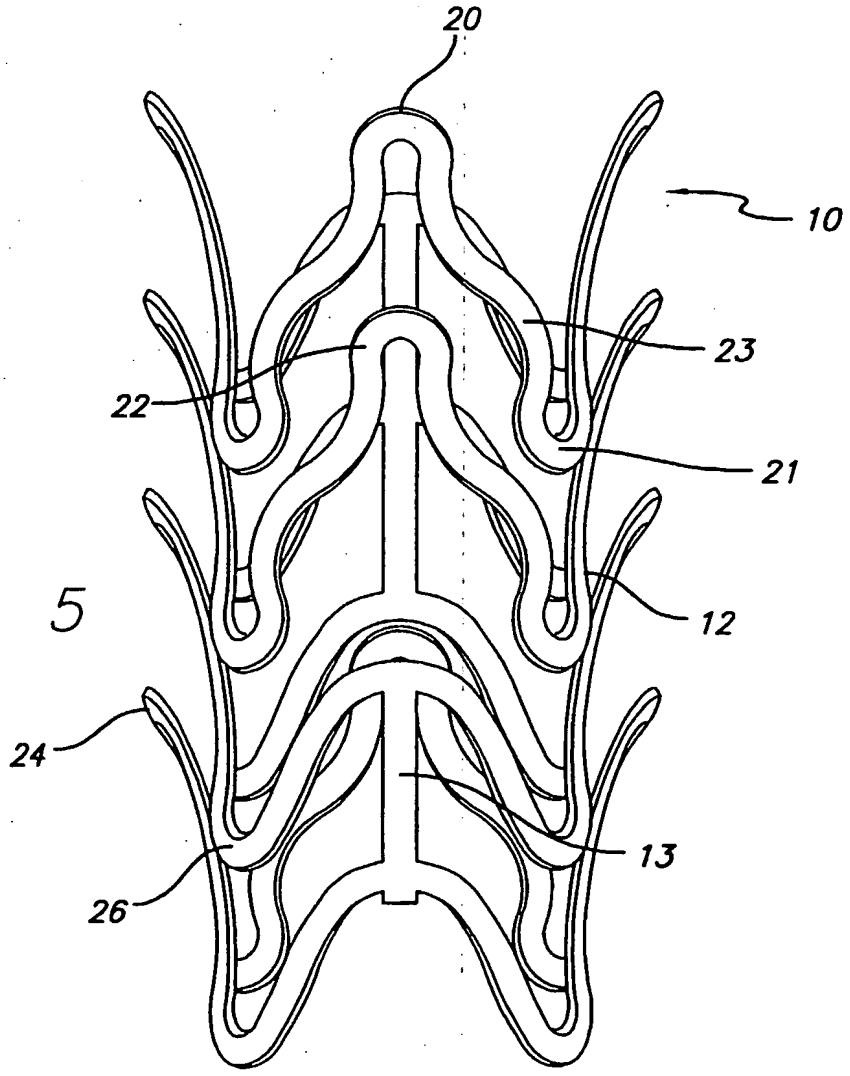

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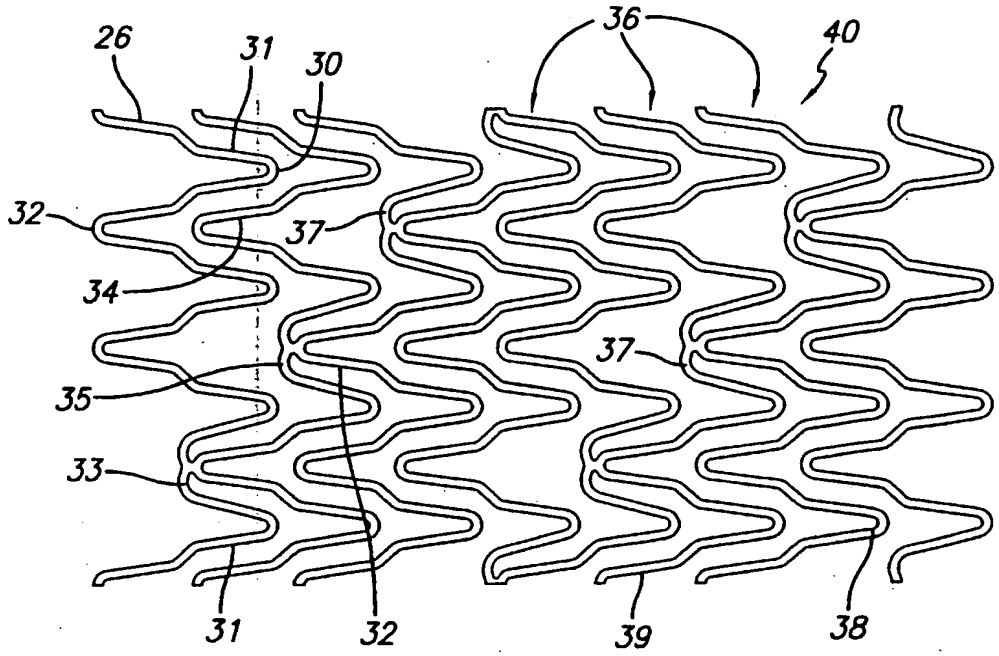
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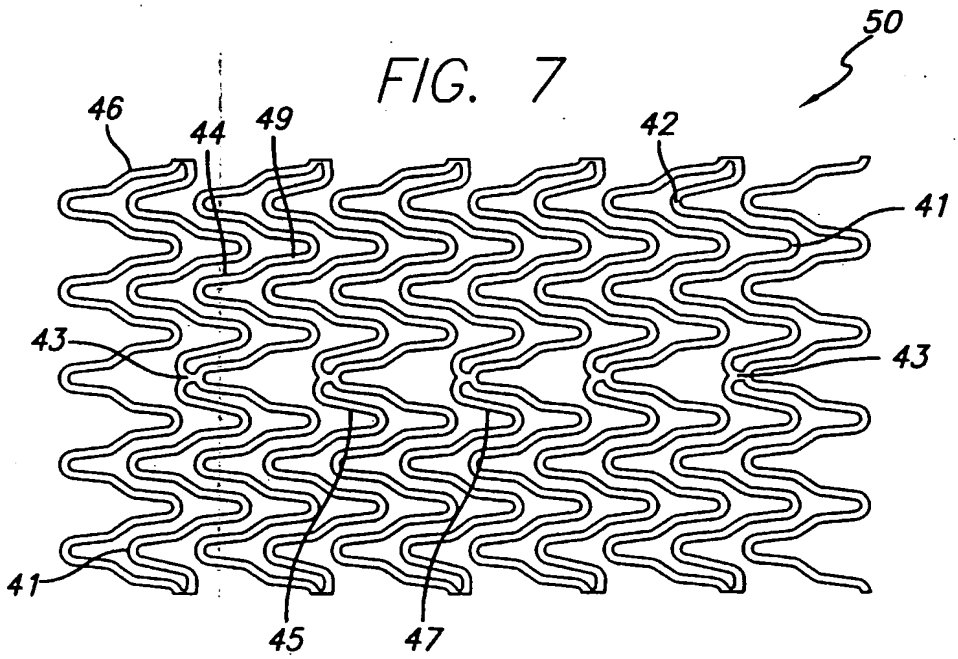
FIG. 7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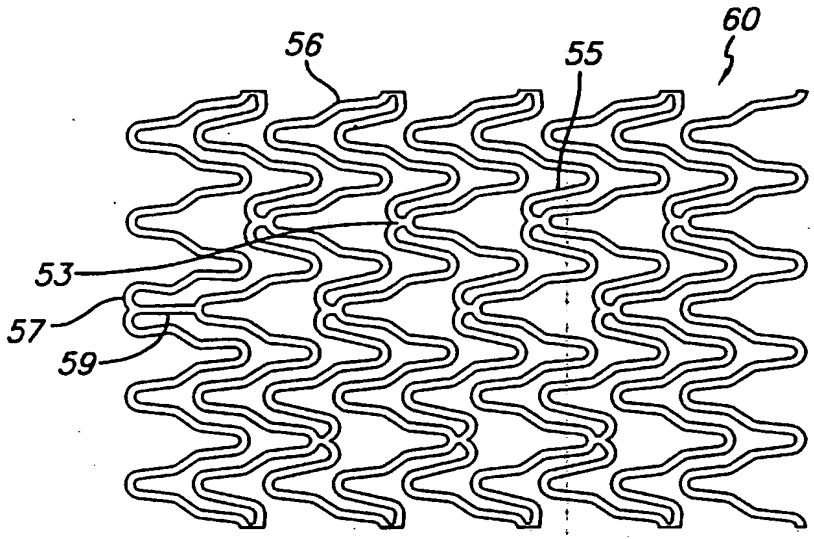


FIG. 8

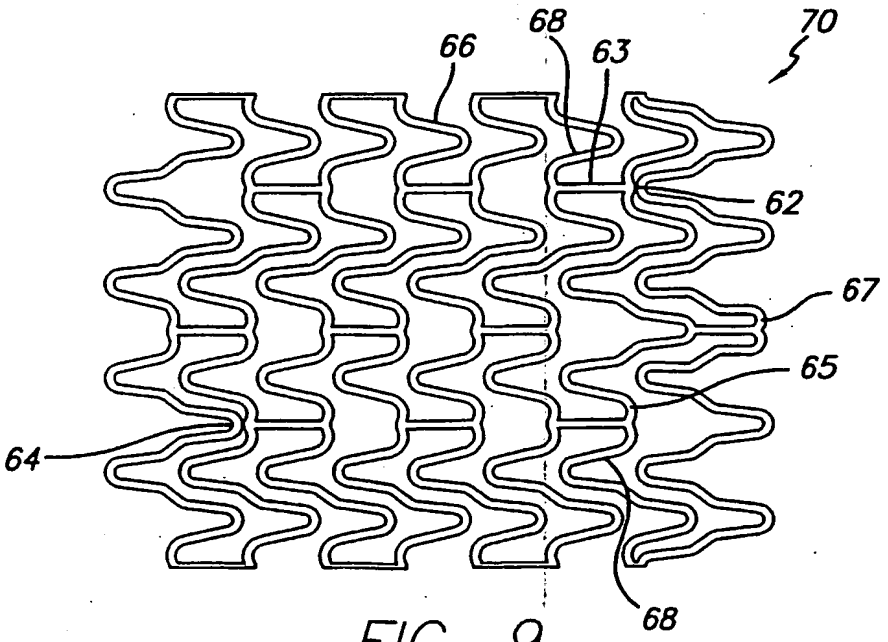


FIG. 9

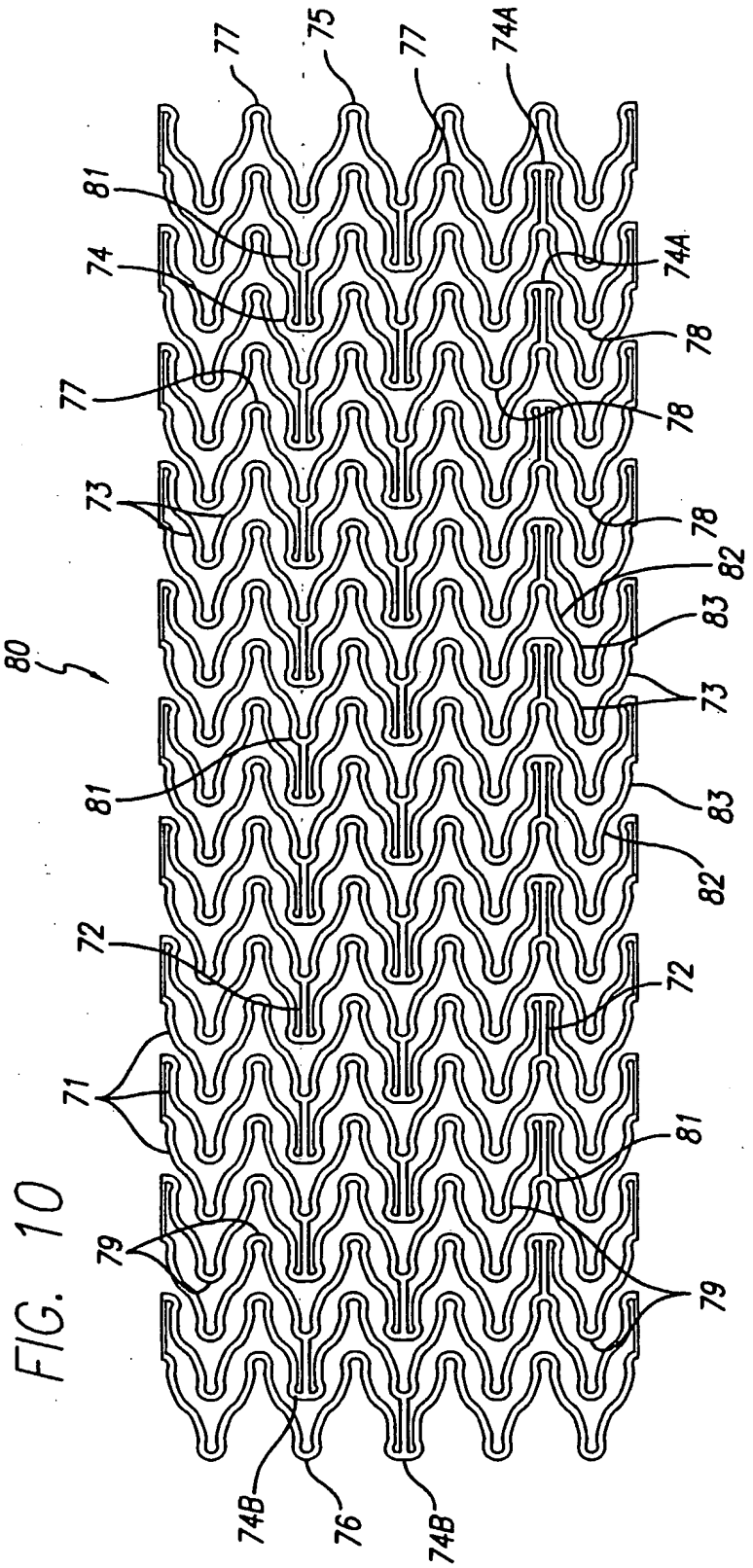


FIG. 10

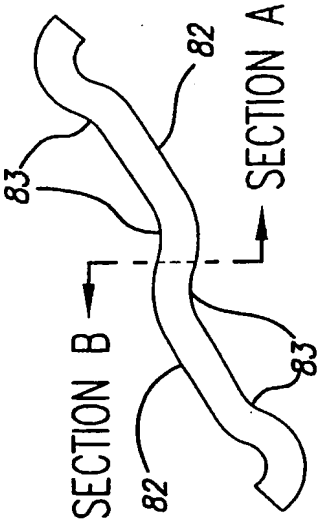


FIG. 10A

FIG. 11

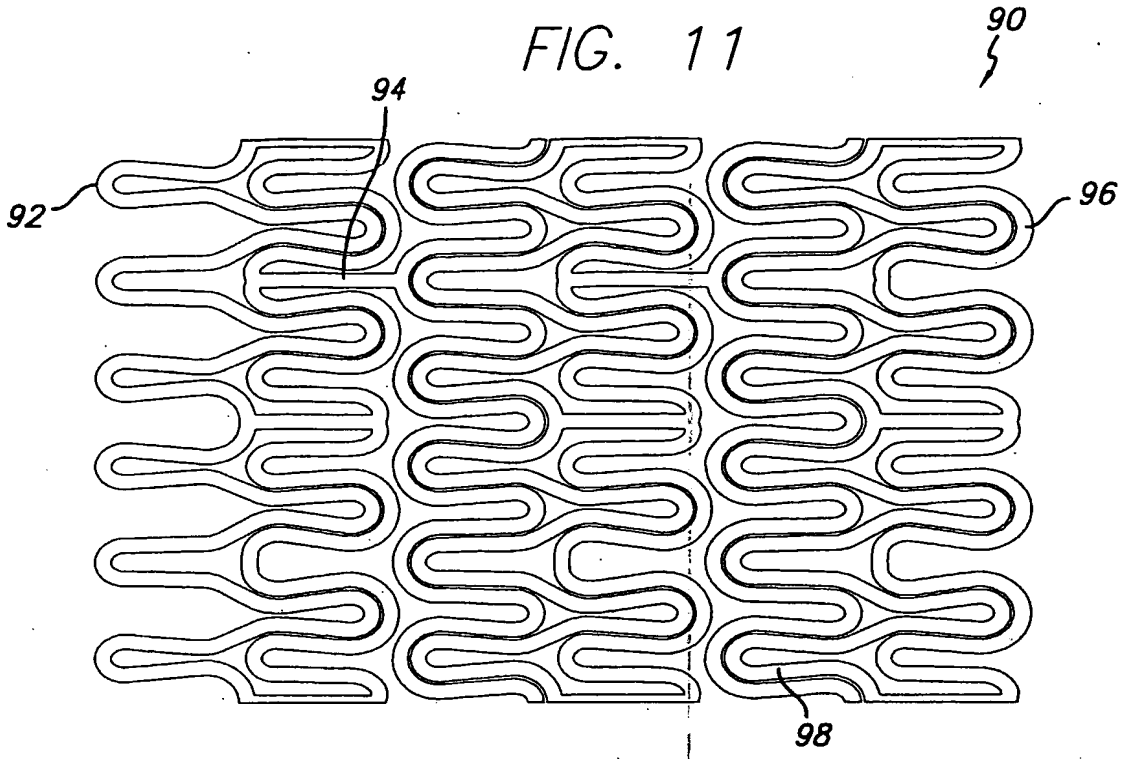
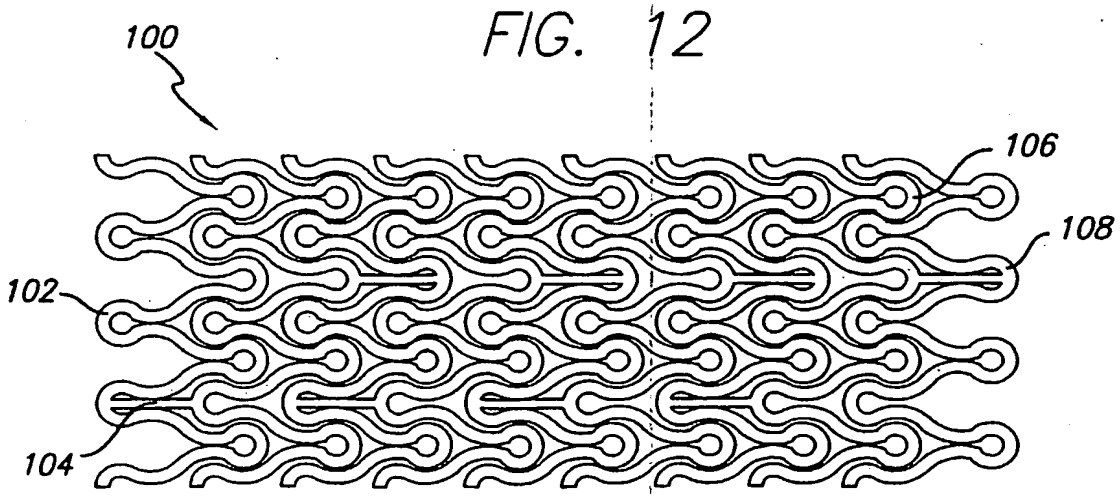


FIG. 12



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/22979

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 03661 A (BRAUN MELSUNGEN AG ;ROUSSIGNE MAURICE (FR); NADAL GUY (FR)) 27 January 2000 (2000-01-27) page 2, line 22 - line 26 page 6, line 33 -page 7, line 6 page 10, line 29 - line 34 page 11, line 33 -page 12, line 5 figure 2 ---	1-4,7, 10, 15-20, 23,24
X	US 5 928 280 A (HANSEN PALLE M ET AL) 27 July 1999 (1999-07-27) column 7, line 35 - line 54 column 8, line 60 - line 68 figures 1,2 --- -/--	1-4,7, 11, 15-20, 23,24

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 November 2003	27/11/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Amaro, H

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/22979

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 375 676 B1 (COX DANIEL L) 23 April 2002 (2002-04-23) the whole document _____	1-4,7,9, 10, 15-20, 23,24

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
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